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09/682,249	08/09/2001	Guerry L. Grune		1874

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GUERRY LEONARD GRUNE  
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EXAMINER

LAMM, MARINA

ART UNIT PAPER NUMBER

1616

DATE MAILED: 11/04/2003

KG

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/682,249

Applicant(s)

GRUNE, GUERRY L.

Examiner

Marina Lamm

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 20 August 2002 and 15 August 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-26 and 28-48 is/are pending in the application.
- 4a) Of the above claim(s) 12-24, 29-40, 42, 44, 46 and 48 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 1-11, 25, 26, 28, 41, 43, 45 and 47 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

Art Unit: 1616

### **DETAILED ACTION**

Acknowledgment is made of the amendment and arguments filed 8/15/03. Claims pending are 1-26 and 28-48. Claim 27 has been cancelled. Claims 12-24 remain withdrawn from consideration as directed to non-elected invention. Claims 1-11, 25 and 26 have been amended. Claims 28-48 are new.

#### ***Election/Restrictions***

1. Newly submitted claims 29-40, 42, 44, 46 and 48 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the inventions are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. In the instant case, invention claimed in claims 29-40, 42, 44, 46 and 48 has separate utility such as sunscreen composition. See MPEP § 806.05(d).

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 29-40, 42, 44, 46 and 48 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

#### ***Information Disclosure Statement***

2. The cites No. 2, 3, 8-11 and 13-22 cited in the IDS filed 8/22/02 have been reviewed but will not be cited because they do not include author's name and/or title.

#### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

Art Unit: 1616

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 7, 26, 28, 41, 45 and 47 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 7 as amended introduces new matter as it uses the phrase "zinc oxide has a primary particle size of less than 30 nm". There is no support in the specification for this limitation. The limitation "zinc oxide has a primary particle size of less than 30 nm" was not described in the application as filed, and persons skilled in the art would not recognize in the applicant's disclosure a description of the invention as presently claimed. The specification states that titanium dioxide, zinc oxide or combinations thereof can be used as inorganic sunscreens. Further, the specification discloses preferable diameter of titanium dioxide particles of less than about 300 nm. See [0068]. Further, original Claim 7 recites particle size of titanium dioxide particles of less than about 30 nm. However, neither specification nor original claims discloses the presently claimed particle size of zinc oxide. Therefore, it is the examiner's position that the disclosure does not reasonably convey that the inventor has possession of the subject matter of the amendment at the time of filing of the instant application.

Claim 26 as amended introduces new matter as it uses the phrases "greater than or equal to 2% of an inorganic sun-block", "greater than or equal to 0.5% of an emollient",

Art Unit: 1616

“greater than 0.5% of an oil component” and “essential oil derived from earth grown substances.” There is no support in the specification for these limitations. The limitations “greater than or equal to 2% of an inorganic sun-block”, “greater than or equal to 0.5% of an emollient”, “greater than 0.5% of an oil component” and “derived from earth grown substances” were not described in the application as filed, and persons skilled in the art would not recognize in the applicant’s disclosure a description of the invention as presently claimed. With respect to the claimed ranges, the original disclosure recites the ranges of from about 2% to about 25%, preferably from about 2% to about 15% and most preferably from about 3% to about 10% of an inorganic sun-block (see [0068] and original Claim 26); from about 0.5% to about 10% of an emollient (see original Claim 26); and from about 0.1% to about 10%, preferably from about 1% to about 5% and most preferably from about 2% to about 3% of an essential oil (see [0066]), but does not disclose the presently claimed open-ended ranges of the ingredients. Further, the original disclosure does not recite essential oils “derived from earth grown substances”. Therefore, it is the examiner’s position that the disclosure does not reasonably convey that the inventor has possession of the subject matter of the amendment at the time of filing of the instant application.

Claim 28 as amended introduces new matter as it uses the phrase “carrier oil, or an essential oil, or both derived from earth grown substances.” There is no support in the specification for this limitation. The original disclosure does not recite carrier oil or essential oils “derived from earth grown substances”. Therefore, it is the examiner’s position that the disclosure does not reasonably convey that the inventor has possession of the subject matter of the amendment at the time of filing of the instant application.

Art Unit: 1616

New Claim 41 introduces new matter because the following ingredients of the claimed composition were not disclosed in the original disclosure: glycerin, beeswax, an enzyme concentrate, vitamin D, xanthan gum, magnesium silicate, grapefruit seed extract, rosemary extract, cinnamon extract and bearberry extract. New Claim 45 introduces new matter because the following ingredients of the claimed composition were not disclosed in the original disclosure: enzyme or enzyme mixture. New Claim 47 introduces new matter because the following ingredients of the claimed composition were not disclosed in the original disclosure: vegetable glycerin, beeswax, orange wax, buttermilk powder, sodium borate, xanthan gum, honey, glucose, enzyme or enzyme mixture, and rosemary extract. It is the examiner's position that the disclosure does not reasonably convey that the inventor has possession of the subject matter of the amendment at the time of filing of the instant application.

***Claim Rejections - 35 USC § 102***

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
6. Claims 1, 4-6, 8-10 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Lukenbach et al. (US 5,980,871).

Lukenbach et al. teach sunscreen compositions containing from about 2 to about 25% of an inorganic sunscreen agent such as titanium dioxide, zinc oxide or mixtures thereof, from about 0.5 to about 10% of an anionic emulsifier such as sodium stearate, and from about 0.5 to about 10% of an oil component comprising a carrier oil and an emollient. See Claim 16; col. 5, lines 15-67; col. 6, lines 1-36. The ratio of inorganic sunscreen agent to oil component is from about 0.3:1 to about 1:1. See Claim 27; col. 6, lines 37-40. The Lukenbach's

Art Unit: 1616

compositions have a pH of above 5 (for example, 6.42 or 7) and SPF of at least 10. See Claims 12-14; col. 6, lines 46-54; Examples 96 and 97. The compositions may additionally contain antimicrobial agents, depigmenting agents, anti-aging agents, etc. See col. 6, lines 61-65; Claim 19. The limitation "non-endocrine disrupting" in Claims 1, 4 and 8 is inherent in the compositions of Lukenbach et al. because the reference teaches the same ingredients as disclosed in the instant specification, i.e. zinc oxide, titanium oxide, sodium stearate, isopropyl PPG-2 isodeceth-7 carboxylate, etc.

Thus, Lukenbach et al. teach each and every limitation of Claims 1, 4-6, 8-10 and 28.

***Claim Rejections - 35 USC § 103***

7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

8. Claims 2, 3 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lukenbach et al. in view of Strickland et al. (US 5,824,659).

Lukenbach et al. teach sunscreen compositions as discussed above. With respect to Claim 25, Lukenbach et al. teach a one-vessel process for making the sunscreen composition comprising first creating the water phase and then adding a carrier oil when the temperature of the water phase reaches a certain level, then adding an inorganic sunscreen agent and heating and mixing said resultant composition. See col. 8, lines 1-35. Although, the inorganic sunscreen is added after the addition of oil phase in the process of Lukenbach et al. (as opposed to before the addition of the oil phase in the instant claims), there appears to be no criticality associated with the order in which the ingredients are added. Lukenbach et al. do not teach aloe of the instant claims. However, Strickland et al. teach Aloe Vera (aloe barbadensis

Art Unit: 1616

Miller) extracts containing cytoprotective oligosaccharides useful to protect skin from damaging effects of UV radiation. See col. 1, lines 11-15; Claim 1. The Aloe Vera gel of Strickland et al. is produced at low temperatures and "activated" under freezing temperatures. See col. 15, lines 29-33; col. 16, Example 1; col. 13, line 62. One of ordinary skill would have been motivated to employ aloe extract of Strickland et al. in sunscreen compositions of Lukenbach et al. with a reasonable expectation of beneficial results such as additional protection of the skin against UV light.

9. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lukenbach et al. in view of Fardell et al. (WO 93/11742) supplied by the Applicant.

Lukenbach et al. applied as above. Lukenbach et al. do not teach zinc oxide having a primary particle size of less than 30 nm as claimed in the instant claim. However, Fardell et al. teach substantially transparent sunscreen compositions comprising a metal oxide, such as zinc oxide or titanium oxide, or both, having a mean primary particle size most preferably from about 15nm to about 30nm. See p. 2, lines 20-24; p. 7, lines 23-28. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the sunscreen compositions of Lukenbach et al. such that to employ zinc oxide having a primary particle size of 15-30nm. One having ordinary skill in the art would have been motivated to do this to obtain substantially transparent compositions that are "aesthetically pleasing to the user" as suggested by Fardell et al.

10. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lukenbach et al.



Lukenbach et al. applied as above. The reference is silent with respect to the IRF and NED of the composition. However, the sunscreen compositions of Lukenbach et al. contain the same ingredients as the claimed compositions (see above) and are used in skin care for the same purpose as the claimed compositions, i.e. for providing "adequate and safe protection for human skin." See col. 3, lines 60-63. Therefore, the determination of optimal IRF and NED of the composition by routine experimentation is obvious to one of ordinary skill in this art. There appears to be no criticality in the ratios since the prior art recognizes and obtains the same results. One having ordinary skill in the art would have been motivated to do this because the reference demonstrates how to obtain the desired high sun protection and safety of the composition. No unexpected result is seen that would demonstrate an unusual result over the generic teachings of the "adequate and safe protection" in the reference.

11. Claim 45 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lukenbach et al. in view of Guerrero et al. (US 5,505,935) and Siddiqui et al. (US 6,015,548).

Lukenbach et al. applied as above. Lukenbach et al. does not teach enzyme or enzyme mixture claimed in the instant claim. However, Guerrero et al. teach using enzymes such as superoxide dismutase in sunscreen compositions. See col. 6, lines 44-46. Siddiqui et al. teach that it is known to incorporate superoxide dismutase into sunscreen products for its antioxidant properties. See col. 3, lines 28-31. Further, Siddiqui et al. teach that a mixture of antioxidants, including superoxide dismutase, improves sun protection of sunscreen compositions. See col. 4, lines 6-11, 22-44. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the sunscreen compositions of Lukenbach et al. such that to employ superoxide dismutase. One having

Art Unit: 1616

ordinary skill in the art would have been motivated to do this to obtain sunscreen compositions having improved sun protection as suggested by Siddiqui et al.

12. Claims 26 and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lukenbach et al. in view of Nakatsu et al. (US 5,965,518).

Lukenbach et al. applied as above. Lukenbach et al. teach using carrier oils, fragrances and/or antimicrobial agents in their compositions. See col. 6, lines 9-11, 55-65. Lukenbach et al. do not teach essential oils of the instant claims. However, Nakatsu et al. teach fragrance compositions having antimicrobial properties which can be used in a variety of products, including sunscreens, said fragrance compositions comprising essential oils. See Abstract; col. 1, lines 54-65; col. 3, lines 47-67; col. 4, lines 1-5; Claim 18. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the sunscreen compositions of Lukenbach et al. such that to employ essential oils of Nakatsu et al. One having ordinary skill in the art would have been motivated to do this to obtain sunscreen compositions having pleasant smell and antimicrobial activity as suggested by Nakatsu et al.

13. Claim 47 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lukenbach et al. in view of Nakatsu et al. as applied to claim 26 above, and further in view of Strickland et al.

Lukenbach et al. in view of Nakatsu et al. applied as above. Neither reference teaches a cytoprotective agent derived from an earth grown substance as claimed in the instant claim. However, Strickland et al. teach Aloe Vera extracts containing cytoprotective oligosaccharides useful to protect skin from damaging effects of UV radiation. See col. 1, lines 11-15; Claim 1.

Art Unit: 1616

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to further modify the sunscreen compositions of Lukenbach et al. such that to employ Aloe Vera extracts of Strickland et al. One having ordinary skill in the art would have been motivated to do this to obtain sunscreen compositions having an improved protection of the skin against UV light as suggested by Strickland et al.

***Response to Arguments***

14. Applicant's arguments with respect to the Luckenbach reference have been fully considered but they are not persuasive.

The Applicant argues that the reference "contains no limitations regarding non-endocrine disrupting agents, nor does the reference make mention of the existence of endocrine substances and therefore is not the same invention." In response, it is noted that the reference teaches the same ingredients as claimed in the instant invention, i.e. zinc oxide, titanium dioxide and sodium stearate. Therefore, the limitation "non-endocrine disrupting" with respect to these substances is inherent in the reference. The Court in In re Papsech has held that a compound and all of its properties are inseparable. 315 F2d. 381, 137 USPQ 43, (CCPA 1963). Further, the Applicant argues that Luckenbach "makes no mention of any method of making a non-endocrine disruptive composition." In response, it is noted that the method taught in the reference is substantially the same as one claimed in the instant Claim 2, i.e. one-vessel method as discussed above. Although, the inorganic sunscreen is added after the addition of oil phase in the process of Lukenbach et al., there appears to be no criticality associated with the order in which the ingredients are added, as long as the oil phase is added to the water phase. Further, the limitation "non-endocrine disrupting composition" is inherent

Art Unit: 1616

to the compositions of Lukenbach et al. because their compositions contain the same ingredients as claimed in the instant claims, i.e., zinc oxide and/or titanium dioxide and oil component. Further, it is noted that the claimed compositions are not limited to non-endocrine disrupting ingredients as the Applicant uses the open-end term "comprising".

15. Upon reconsideration, the rejection over Wenker reference has been withdrawn. The compositions of Wenker contain none or very low amount of titanium dioxide, i.e. 0-0.5% by volume, and, therefore, it does not appear that they will be "capable of protecting skin from harmful effects of radiation including sunlight and ultraviolet light" as required by the instant claims. Further, Strickland et al. teach that native Aloe vera gel is minimally active in preventing UVB-induced damage to the skin, and requires "activation" to a protective state. Therefore, the presence of Aloe vera gel in the compositions of Wenker also does not impart the UV-protecting property to the compositions.

### *Conclusion*

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

Art Unit: 1616

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marina Lamm whose telephone number is (703) 306-4541.

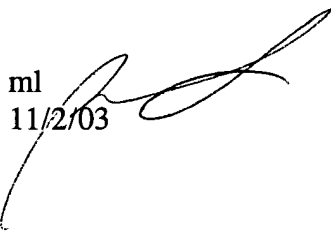
The examiner can normally be reached on Monday to Friday from 9 to 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached at (703) 308-2927.

The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

ml  
11/2/03



THURMAN PAGE  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600